

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

SPECGX LLC,

Plaintiff,

v.

BARBARA D. UNDERWOOD, in her official capacity as acting Attorney General of the State of New York; and HOWARD A. ZUCKER, in his official capacity as Commissioner of Health of the State of New York,

Defendants.

Civil Action No.

**COMPLAINT FOR
DECLARATORY AND INJUNCTIVE RELIEF**

INTRODUCTION

1. Plaintiff SpecGx LLC (“SpecGx”) brings this complaint against Barbara D. Underwood, in her official capacity as acting Attorney General for the State of New York, and Howard A. Zucker, in his official capacity as Commissioner of the Department of Health of the State of New York (together, the “Defendants”), to declare unconstitutional the Opioid Stewardship Act (“OSA”), N.Y. Pub. Health Law § 3323 (McKinney) (effective July 1, 2018), and to permanently enjoin its enforcement against SpecGx.

2. The OSA imposes on manufacturers and distributors of FDA-approved opioid medications a class-wide penalty totaling \$100 million. In doing so, the OSA violates critical constitutional limits. The OSA penalizes manufacturers and distributors for entirely *lawful* conduct—selling FDA-approved opioid medications for physician-prescribed purposes, in amounts determined by the U.S. Drug Enforcement Administration (“DEA”) to be necessary for legitimate uses. This legislative determination of guilt opts for scapegoating instead of genuinely grappling with a highly complicated social issue regarding the *misuse* of opioid-based substances, and, without justification, punishes parties who are working to ensure the *proper* usage of these important pain-management medications.

3. The OSA euphemistically calls the penalty imposed on each individual manufacturer or distributor that entity’s “Ratable Share.” Confirming, however, that a manufacturer’s or distributor’s Ratable Share is a penalty, the OSA forbids manufacturers or distributors from increasing the price of its medications in order to pass on any portion of its Ratable Share to their New York purchasers, including the “ultimate users.”

4. The New York legislature’s unprecedeted action offends constitutional protections and conflicts with several federal statutory programs. By imposing, without any

procedural protections, a confiscatory penalty on manufacturer and distributor conduct that federal law expressly authorizes and encourages, the OSA will inevitably deter that conduct. For manufacturers of low-priced generic opioids, the effect is especially stark. As became clear from SpecGx's OSA assessment for 2017, which SpecGx received on October 18, 2018, the OSA penalty associated with the sale of SpecGx's highest volume generic opioids *exceeds or is just below the revenue* (not even accounting for costs) that SpecGx generates from selling those high volume generic opioid medications into New York. Because the OSA forbids manufacturers and distributors from collecting the OSA penalty from New York purchasers, unless the OSA is enjoined, SpecGx's continued sale of generic opioids in New York *will result in financial loss* to SpecGx.

5. Thus, the practical effect of the OSA's unprecedented combination of penalties and pricing restraints will be to either (i) force manufacturers to choose between losing money on the sale of low-priced generic opioids in New York or withdrawing those products from the New York market, in contravention of federal law and to the great detriment of patients; or (ii) force manufacturers and distributors of generic opioid medications to shift the burden of paying New York's Ratable Share to consumers in *other* states, in violation of the dormant Commerce Clause.

6. The OSA was the result of a legislative compromise designed to selectively penalize manufacturers and distributors for their lawful participation in a complicated, interconnected system by which opioids are regulated, distributed, prescribed, and dispensed, involving numerous other actors, including law enforcement, DEA, pharmacies, and physicians. The OSA's unprecedented combination of penalties and pricing restraints, if allowed to be enforced, would radically disrupt the pharmaceutical marketplace both in New York and elsewhere, frustrating the policies embodied in several federal statutes.

7. SpecGx's generic opioid products are subject to nationwide regulation by the federal government, and the states are not free to prohibit their sale. Under the Food, Drug, and Cosmetic Act ("FDCA") and regulations of the Food and Drug Administration ("FDA"), the FDA must first review and approve medicines as safe and effective for use in the United States before they can be manufactured and sold. Here, the FDA has approved SpecGx's generic medications pursuant to statutes that specifically encourage the manufacture and sale of inexpensive therapeutic equivalents to brand name drugs. Moreover, the amount of opioid products each manufacturer is permitted to produce and sell is based on the DEA's determination, pursuant to statutory authority, of the level of production necessary to serve legitimate medical, scientific, and industrial needs in the United States.

8. No state could simply ban the sale of these generic opioids. Yet New York has, in effect, done precisely that. The OSA will render the sale of generic opioids economically unfeasible in the State, thereby eliminating (or at least drastically decreasing) the supply of critical, affordable pain medication available to patients in New York, in contravention of federal law. The only way this outcome will *not* occur is if manufacturers or distributors are somehow able to offset the OSA's costs by selectively raising prices in markets outside of New York—which would effectively shift the cost of New York's program onto consumers outside New York, in violation of the dormant Commerce Clause. Either way, New York's OSA cannot stand.

9. The unconstitutional effects of the OSA are highlighted by a letter dated October 10, 2018, from AmerisourceBergen Corp. ("AmerisourceBergen") to Mallinckrodt LLC (SpecGx's sole member),¹ informing Mallinckrodt that AmerisourceBergen would no longer

¹ SpecGx LLC was formed on November 14, 2016, as a wholly owned subsidiary of Mallinckrodt LLC. AmerisourceBergen Corp. likely addressed this letter to Mallinckrodt rather than SpecGx because of AmerisourceBergen's previous contracts with Mallinckrodt.

distribute SpecGx's opioid products from its Ohio distribution center to New York, unless SpecGx agrees to pay the OSA Ratable Share attributable to SpecGx's opioid products. SpecGx must either distribute to AmerisourceBergen's New York distribution center, in which case SpecGx would be responsible for the first sale into New York and bear the burden of the OSA Ratable Share, or reimburse AmerisourceBergen for the same Ratable Share. AmerisourceBergen's letter is the expected, natural consequence of the OSA's prohibition against passing the Ratable Share onto New York consumers. Rather than bear that cost itself, AmerisourceBergen has chosen to avoid any sales of SpecGx opioid products into New York for which AmerisourceBergen would bear the Ratable Share liability. Accordingly, SpecGx would be responsible for paying the penalty for all opioid medication it distributes to AmerisourceBergen that ultimately ends up in New York.

10. Yet SpecGx itself cannot absorb the Ratable Share either. As described below, the Ratable Share allocated to each milligram of morphine equivalent ("MME") of key high-volume products is greater than the average manufacturer price paid by wholesalers to manufacturers for those products. Thus, AmerisourceBergen's letter makes clear that SpecGx must either (a) cease selling its generic opioids in New York, or (b) recover the New York OSA assessment from non-New York customers. Option (b) would violate dormant Commerce Clause principles, but even if it did not, such price differentiation is not practically feasible. As a consequence, in order to avoid sales at a loss, SpecGx would be forced to cease sales of its generic opioids in New York unless this Court grants injunctive relief from the OSA.

11. The facts identified in this Complaint illustrate the serious constitutional defects in the OSA, many of which are already addressed in litigation brought by the Healthcare Distribution Alliance (*Healthcare Distribution Alliance v. Zucker*, No. 1:18-cv-6168 (S.D.N.Y. filed July 6, 2018)) and by the Association of Accessible Medicines (*Ass'n for Accessible Medicines v.*

Underwood, No. 1:18-cv-8180 (S.D.N.Y. filed Sept. 7, 2018)). The purpose of this Complaint is not to reiterate the well-founded constitutional challenges set forth in those complaints. Rather, SpecGx's focus is on the immediate, constitutional problem that has come into clear focus only recently, as the OSA takes practical effect. Namely, it has become evident the amount owed under the OSA for the highest volume products exceeds or is just below the selling price for those products. Moreover, it has become clear that generic manufacturers will, one way or another, be forced to bear the burden for paying the vast majority of the \$100 million Opioid Stewardship Payment. Because the OSA prohibits generic manufacturers from passing the OSA charge on to purchasers, the OSA makes it economically *impossible* for generic manufacturers to sell generic opioid medications in the state of New York.

12. As a consequence, SpecGx faces an imminent decision whether to stop sales into the state of New York or try to pass the OSA payment on to out-of-state customers. In any of these scenarios, the OSA runs afoul of the Federal Constitution. And, to the extent it drives low-cost generic drugs out of the New York market, it will also deprive New Yorkers of affordable medication while driving up the cost of healthcare as patients are forced to purchase branded products that are often several times more expensive than generic versions of the same product. This Court's immediate intervention is thus critical. SpecGx requests that the Court step in now, before the OSA begins to disrupt supplies of federally approved and medically necessary medicines, to declare that the OSA violates the Supremacy Clause and the Commerce Clause, and to enjoin its implementation and enforcement against SpecGx.

PARTIES

13. Plaintiff SpecGx LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 385 Marshall Ave., Webster Groves,

Missouri 63119. SpecGx develops, manufactures, and sells pharmaceutical products and therapies, including generic opioid medications. At present, it sells and distributes generic opioid medications in New York State.

14. Defendant Barbara D. Underwood is sued in her official capacity as the acting Attorney General of the State of New York. In that official capacity, she has the authority to investigate and prosecute violations of the laws of the State of New York, including the OSA. *See* N.Y. Exec. Law § 63 (McKinney).

15. Defendant Howard A. Zucker, M.D., J.D., is sued in his official capacity as the Commissioner of Health for the State of New York. In that official capacity, he oversees the Department's administration of the OSA and assessment of "Ratable Share" penalties. In addition, he has the specific authority to "impose a penalty not to exceed one million dollars per incident" on any manufacturer or distributor that has "passed on" its "Ratable Share, or any portion thereof, . . . to a purchaser," including the ultimate user of the medications. N.Y. Pub. Health Law § 3323(10)(C).

16. In enforcing, administering, and adhering to the Act, Defendants and those subject to Defendants' supervision, direction, and/or control will at all relevant times be acting under color of state law.

JURISDICTION AND VENUE

17. This action seeks declaratory relief under the Federal Declaratory Judgment Act, 28 U.S.C. § 2201.

18. SpecGx's causes of action arise under the United States Constitution, the Court's equitable authority under *Ex parte Young*, 209 U.S. 123 (1908), and 42 U.S.C. § 1983. The Court has jurisdiction under 28 U.S.C. § 1331.

19. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(3).
20. An actual, justiciable controversy currently exists between the parties concerning the constitutionality of the OSA.
21. A declaration that the OSA is inconsistent with federal statutes, and is unconstitutional under the Supremacy Clause and the Commerce Clause will resolve this controversy.
22. A permanent injunction preventing enforcement of the OSA will prevent SpecGx from being injured by a law that interferes with federal law and violates the Supremacy Clause and the Commerce Clause.

FACTUAL ALLEGATIONS

SpecGx's Sale of Generic Opioid Products in the State of New York

23. SpecGx, a generic pharmaceutical manufacturer, plays a crucial role in the healthcare market in New York and throughout the United States.
24. Through its *lawful* manufacture and sale of FDA-approved, safe and effective, generic, opioid-based pharmaceutical products—including generic opioid medications that are subject to the OSA—SpecGx helps to ensure access to cost-effective, affordable prescription medications that physicians and other registered healthcare providers have long prescribed and relied on to provide pain management to seriously ill New York patients (including cancer patients, post-surgical patients, hospice care patients, and others suffering from acute, chronic, or persistent pain). In that manner, SpecGx's generic products play a critical role in controlling the otherwise steadily increasing costs associated with prescription drugs. Reducing the supply of generic alternatives for prescription opioids in New York will almost certainly increase the demand for

branded opioid pain medications and result in a significant increase in the overall prescription drug prices and ultimately healthcare spending in New York.

25. According to publicly available Average Manufacturer Price or “AMP” data from 2017, the average manufacturer’s sales price for many generic opioid medications, including the principal ones, is mere pennies per tablet. A prescription drug’s AMP is defined as “the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.” 42 C.F.R. § 447.504. Therefore, the AMP takes into account rebates, chargebacks, discounts, and other required price concessions. All manufacturers, like SpecGx, report AMP data monthly for all covered drugs (including the generic opioid medications covered by the OSA) to the Centers for Medicare & Medicaid Services (“CMS”). CMS compiles this data reported by manufacturers and calculates and publishes weighted average AMPs² for each of the covered drugs.

26. Generic pharmaceutical products, like the opioid medications manufactured and sold by SpecGx, offer the safety and efficacy of their brand-name counterparts at substantially less expensive prices. Under a well-established federal regulatory framework, SpecGx manufactures these generic products at lower costs—without the significant development costs, complex regulatory processes, sales force promotion to physicians, and other overhead carried by brand-name manufacturers. But, because it operates in a highly competitive market environment, SpecGx also sells its low-priced generic opioids at much lower profit margins than their brand counterparts. The availability of several (often many) generic pharmaceutical products that are pharmacologically interchangeable with SpecGx’s products creates market competition that drives

² “Weighted average AMP” refers to the average AMP weighted by volume.

prices for generic prescription drugs down to a fraction of the brand-name equivalent. The availability of low-priced generics in turn typically “genericizes” approximately 90% of the market, thus making whole categories of medicines more affordable and accessible to those in need.

27. These generic prescription drugs are sold by two primary paths: (i) the manufacturer sells the products to wholesale distributors under terms of a negotiated contract, after which the wholesale distributor then re-sells the product to retail pharmacies or other providers; and (ii) the manufacturer may also sell to national or regional pharmacy chains, hospitals, and other healthcare facilities. For SpecGx, a very high percentage of its sales are to wholesale distributors, with the majority of those sales consummated outside New York, and those wholesalers then re-sell the product to retail pharmacies, hospitals, or other healthcare facilities in New York and elsewhere.

New York Assembly Imposes Penalties Through the “Opioid Stewardship Act”

28. In early January 2018, Governor Cuomo proposed to the New York legislature a “comprehensive plan to hold pharmaceutical companies accountable for perpetuating the [opioid] epidemic.”³ This was a shocking statement of intent to punish companies, like SpecGx, that have never been found to be culpable for “perpetuating the opioid epidemic” through any adjudicative process. Rather, the proposal reflected an intent to convict an entire industry of wrongdoing in the court of popular opinion without affording the companies any opportunity to defend themselves,

³ Press Release, Gov. Andrew M. Cuomo, Governor Cuomo Outlines 2018 Agenda: Realizing the Promise of Progressive Government (Jan. 3, 2018), <https://www.governor.ny.gov/news/governor-cuomo-outlines-2018-agenda-realizing-promise-progressive-government>.

and seemingly without any appreciation of the critical role these companies play in providing lawful, cost-effective, FDA-approved medications to patients in need of pain management.

29. The proposal included an “opioid epidemic surcharge”⁴ of two cents on every MME sold. Under that proposal, the DEA registrant making the first sale into New York would have been responsible for the surcharge, and the proceeds would have been directed to an Opioid Prevention and Rehabilitation Fund (which would have been used to fund existing state programs).⁵ Similar to the later enacted OSA, the Governor’s proposal prohibited the entity making the first sale into New York from passing this surcharge on to the ultimate consumer of the medication.⁶

30. At a hearing before the New York State Senate and Assembly finance committees on February 12, 2018, the Chain Pharmacy Association of New York State opposed the proposed surcharge and complained that the surcharge overwhelmingly would burden *in-state* pharmacies.⁷ The Pharmacists Society of the State of New York similarly objected that, although the imposition was “intended to be borne by opioid manufacturers,” “[m]anufacturers . . . are located outside of New York” and “do not sell directly to pharmacies”; as a result, they testified, the proposed

⁴ Press Release, Gov. Andrew M. Cuomo, Governor Cuomo Outlines FY 2019 Budget: Realizing the Promise of Progressive Government (Jan. 16, 2018), <https://www.governor.ny.gov/news/governor-cuomo-outlines-fy-2019-budget-realizing-promise-progressive-government>.

⁵ *Id.*; Andrew M. Cuomo & Robert F. Mujica, Jr., *Stand United to Fight for New York: FY 2019 Executive Budget* 108 (2018), <https://www.budget.ny.gov/pubs/archive/fy19/exec/fy19book/BriefingBook.pdf>.

⁶ Assemb. 9509, 2018 Assemb. pt. CC (N.Y. Jan. 18, 2018).

⁷ Joint Legis. Budget Hearing on Health/Medicaid, 2018–19 Leg. (N.Y. 2018) (statement of Chain Pharmacy Association of NYS) (emphasis added).

surcharge would burden “*in-state* wholesalers” and pharmacies who would not be able to pass the charge on to consumers.⁸

31. No facts were presented and no witnesses were called to substantiate the Governor’s assertion that opioid manufacturers were responsible for “perpetuating the opioid epidemic,” nor were manufacturers afforded the opportunity to rebut that assertion. Instead, the Commissioner of Health repeatedly promised the legislature that the intended target of the proposed “surcharge” was the “pharmaceutical companies,” because “they need to be held accountable.”⁹ One witness encouraged the legislature “to show [pharmaceutical companies] that we can discipline what they do.”¹⁰

32. The Senate subsequently rejected Governor Cuomo’s specific proposal to impose the two-cent surcharge.¹¹ The Assembly, however, suggested increasing the surcharge and providing certain entities (such as in-state pharmacies) exemptions from the surcharge.¹²

33. New York passed the OSA on March 31, 2018, as a “last-minute compromise” between the Senate and Assembly’s proposals, and Governor Cuomo signed the bill on April 12, 2018. No further legislative hearings were held on the compromise bill. By design, the OSA targets opioid manufacturers and distributors to finance the “Opioid Stewardship Fund” in the 2018–2019 state budget. The Opioid Stewardship Fund is a specific-use fund dedicated to programs offered by the New York State Office of Alcoholism and Substance Abuse Services, a

⁸ Joint Legis. Budget Hearing on Health/Medicaid, 2018 Reg. Sess. (N.Y. 2018) (statement of Roxanne Richardson, President, Pharmacist Society of the State of New York).

⁹ Joint Legis. Budget Hearing on Health/Medicaid, 2018 Reg. Sess. (N.Y. 2018) (Commissioner Howard A. Zucker).

¹⁰ Joint Legis. Budget Hearing on Health/Medicaid, 2018 Reg. Sess. (N.Y. 2018) (Steven Safyer, President and CEO, Montefiore Health System).

¹¹ S. Res. 4168, 2018 Reg. Sess. (N.Y. 2018).

¹² Assemb. 9509-B, 2018 Assemb. pt. CC (N.Y. 2018).

state agency that provides services for New York residents affected by wide-ranging addictions. N.Y. State Fin. Law § 97-aaaaa.

34. The Act requires a \$100 million “Opioid Stewardship Payment” to be paid into the Opioid Stewardship Fund each state fiscal year.¹³ N.Y. Pub. Health Law § 3323(1)(a), (3). “All manufacturers and distributors” (*i.e.*, wholesale distributors) that “sell or distribute opioids in the state of New York” (referred to as “Licensees”) must pay a Ratable Share of this Payment. *Id.* § 3323(2). This Ratable Share is calculated through the following volume-based method:

a. “Each manufacturer and distributor . . . that sells or distributes opioids in the State of New York shall provide to the Commissioner [of Health of the State of New York] a report detailing all opioids [it] sold or distributed . . . in the State of New York,” including the gross receipt of all opioids sold and the total number of MMEs sold or distributed. *Id.* § 3323(4).

b. The total amount of MMEs sold or distributed in the State of New York by a given manufacturer or distributor for the preceding calendar year (as reported above) is then divided by the total amount of MME sold in the state of New York by *all* manufacturers and distributors to determine the “licensee payment percentage.”¹⁴ *Id.*

c. Multiplying the licensee payment percentage by \$100 million yields each manufacturer’s or distributor’s Ratable Share. *See id.* § 3323(5)(b).

35. Hypothetically, if a pharmaceutical manufacturer makes the first sale into New York of two million MMEs of ten million MMEs overall sold or distributed into New York, under the OSA, that manufacturer must contribute a “Ratable Share” of \$20,000,000 (or 20% of the

¹³ The OSA has a sunset provision, which provides that the OSA “shall expire and be deemed to be repealed on June 30, 2024.”

¹⁴ This amount excludes opioids that are manufactured in New York state but whose final point of delivery or sale is outside of the state, opioids sold or distributed to certain rehabilitation or hospice entities; or MMEs attributable to buprenorphine, methadone, or morphine. *Id.* § 3323(5)(b).

overall “Opioid Stewardship Fund”). If the manufacturer sells to a wholesale distributor outside of New York, and the distributor then makes the first sale of the opioids into New York, the distributor is liable for the “Ratable Share” on those opioid products. The Department of Health (“DOH”) is to provide the manufacturer or distributor with written notice of its Ratable Share for the prior calendar year by October 15 of each year. *See id.* § 3323(5)(c). The OSA then directs each licensee to “make payments quarterly to the department.” *Id.* § 3323(6).

36. The New York State Department of Health subsequently issued guidance on the interpretation of the OSA. Notably, it clarified that “[t]he intent of the OSA is for all manufacturers and distributors to be responsible for their Ratable Share of opioids sold or distributed for their Ratable Share of opioids sold or distributed into New York” and that “assessments will be based on the initial transaction in the distribution chain when opioids are ***first sold or distributed*** within, or into, New York.”¹⁵

37. The OSA prohibits a manufacturer or distributor from passing on the Ratable Share to purchasers, including the ultimate user of the opioid medication. *See id.* § 3323(10)(c). Section 10(c) states:

Where the Ratable Share, or any portion thereof, has been passed on to a purchaser by a Licensee, the Commissioner may impose a penalty not to exceed one million dollars *per incident*.

Id. (emphasis added). The Department of Health’s guidance document states that this provision “is not intended to apply to price increases that are attributable to other ordinary changes in manufacture or distribution costs.”¹⁶

¹⁵ N.Y. Dep’t of Health, New York State Opioid Annual Assessment Reporting Guidance (2018), https://www.health.ny.gov/professionals/narcotic/opioid_stewardship_act/docs/osa_reporting_guidance_document.pdf.

¹⁶ *Id.*

38. Although the OSA prohibits passing the Ratable Share on to the Licensee's *purchasers*, nothing in the OSA prohibits a Licensee such as a wholesaler from passing the Ratable Share *upstream* to the manufacturer from which the opioid medicines were purchased.

39. Finally, the OSA provides for retroactive application. Although the OSA became effective July 1, 2018, the newly enacted legislation reaches back and penalizes (lawful) conduct that occurred in 2017. Specifically, the OSA directs the Department of Health to calculate manufacturers' first Ratable Share based upon 2017 sales figures, *id.* § 3323(4-A), (5)(c), and obligates manufacturers to remit that 2017 Ratable Share to the Department of Health by January 1, 2019, *id.* § 3323(6).

SpecGx's Ratable Share Calculation

40. On July 31, 2018, in compliance with the OSA, SpecGx submitted an electronic report to the DOH calculating the total assessable MMEs that it sold and distributed into New York in 2017. Based on further guidance from the DOH, SpecGx subsequently amended its report on October 1, 2018 (as amended, the "2017 SpecGx Report").

41. The 2017 SpecGx Report reported that SpecGx sold **115,037,682** assessable MMEs into New York in 2017. The report only covers those MMEs for which SpecGx completed the first sale into New York (that were not subsequently distributed out of New York). The report does not cover MMEs that SpecGx sold to out-of-state distributors that were then sold into New York by the distributors.

42. In October 18, 2018, Joshua S. Vinciguerra, the Director of the Bureau of Narcotic Enforcement at the DOH, sent a letter to SpecGx (the "2017 SpecGx Invoice") to notify SpecGx of its "estimated payment based on [its] ratable share, calculated in accordance with the terms of

the [OSA].” According to the 2017 SpecGx Invoice, SpecGx’s estimated Ratable Share is \$1,256,326.33, which is due to be paid by January 1, 2019.

43. The 2017 SpecGx Invoice permits a calculation of the estimated Ratable Share per MME for all assessable MMEs sold into New York in 2017. SpecGx’s Ratable Share of \$1,256,326.33 is based on 115,037,682 assessable MMEs first sold and distributed by SpecGx into New York. Dividing \$1,256,326.44 by 115,037,682 equals .011. Accordingly, the Ratable Share assessed to all manufacturers and distributors on every MME first sold and distributed into New York is 1.1 cents.

The OSA Forces Generic Manufacturers of Opioid Products to Sell at a Loss

44. Publicly available AMP data based on actual sales transactions shows that given the low prices that prevail in the highly competitive generic pharmaceutical market, the Ratable Share attributable to generic opioids will far exceed the amount of net revenue that generic manufacturers generate through New York sales. Therefore, the prohibition against passing on a manufacturer’s Ratable Share amount to purchasers will force manufacturers of generic opioids to (1) choose between selling at a loss or exiting the New York opioid market, or (2) recover the cost of their Ratable Shares from purchasers *outside* the State of New York.

45. Indeed, for key generic products sold by SpecGx into New York, this 1.1 cent Ratable Share per MME is just under or *exceeds* the weighted AMP per MME, before even accounting for the manufacturer’s costs of production and distribution.

46. SpecGx’s second highest volume opioid medication (by units sold), Oxycodone HCl Tablet 5 mg, has a weighted AMP per MME of .63 cents. The Ratable Share per MME of 1.1 cents is roughly double the weighted AMP per MME. On a per tablet basis, Oxycodone HCl

5 mg was sold in 2017 for approximately 4.7 cents, but the Ratable Share for that tablet would be 8.2 cents.

47. Similarly, SpecGx's third highest volume opioid medication (by units sold), Hydrocodone/Acetaminophen Tablet 10 mg/325 mg, has a weighted AMP per MME of .84 cents, which is still far less than the Ratable Share per MME of 1.1 cents. On a per tablet basis, Hydrocodone/Acetaminophen Tablet 10 mg/325 mg was sold in 2017 for approximately 8.4 cents, but the Ratable Share for the same tablet was 10.9 cents.

48. In these two high volume products, therefore, the Ratable Share exceeds the entire weighted AMP, before even taking into account the costs of production and distribution. Taking those costs into account, the amount of loss on each sale would be even higher. And, because the OSA prohibits manufacturers or distributors from "passing on" their Ratable Share costs, any manufacturer of FDA-approved generic opioid medications that wished to continue selling those products in New York would be forced to sell these products *at a loss*.

49. Even for products where the Ratable Share per MME did not exceed the weighted AMP per MME, the sale would be at a loss if the production and distribution costs required to manufacture and sell the product was greater than the difference.

50. For example, Acetaminophen with Codeine 300 mg/30 mg, the highest volume product sold by SpecGx into New York by unit, had a weighted AMP per MME of 1.31 cents, which is only slightly above the Ratable Share per MME of 1.1 cents. On a per tablet basis, Acetaminophen with Codeine 300 mg/30 mg was sold in 2017 for approximately 5.88 cents, but the Ratable Share for that tablet would be 4.91 cents.

51. The Ratable Share would far exceed any operating margin SpecGx would have on the sale of a tablet of Acetaminophen with Codeine 300 mg/30 mg. As reported by Mallinckrodt

plc to the Securities and Exchange Commission in its annual report, the operating income as a percentage of net sales—calculated by dividing operating income by net sales—was 27.6% for its Specialty Generics segment (which is the segment that primarily consists of SpecGx). Applying that general rate to the AMP of Acetaminophen with Codeine 300 mg/30 mg, the operating margin per tablet would be approximately 1.62 cents (5.88 cents * .276). The Ratable Share per tablet of 4.91 cents thus far exceeds any operating margin SpecGx might receive on the sale of a tablet of that product.

52. Basic economic reality dictates that if a generic manufacturer is guaranteed to *lose money* on its sale or distribution of an opioid medication in New York, it will abandon the New York opioid market completely.

53. The OSA’s disproportionate effect on generic manufacturers is deeply ironic. Public criticism of opioid manufacturers—which apparently motivated the New York Assembly to “punish” them through this legislation—has largely focused on allegedly misleading marketing of branded opioids to doctors. But generic products, by their nature, are not promoted to doctors; they are simply substituted for branded products at the pharmacy counter, making generic manufacturers a particularly inappropriate target for this form of punishment.

54. Because of the OSA’s “no pass on” prohibition, the only economically feasible alternative to abandoning the New York opioid market would be for the manufacturer to “pass on” its Ratable Share amount to purchasers and patients *outside* of New York. For example, a generic manufacturer charged with a \$20 million Ratable Share amount might seek to incrementally increase its sales prices, or perhaps only its sales prices for transactions occurring outside New York. Even assuming that “passing on” Ratable Share amounts outside New York is allowed by the OSA—the OSA would be even more patently unconstitutional under the dormant Commerce

Clause if it purported to directly regulate pricing outside New York—it is far from clear that, under the nationwide pricing ecosystem that has developed over several decades, a manufacturer or distributor actually could succeed in forcing non-New York purchasers to absorb the cost of its OSA penalties. Indeed, fundamental tenets of competition might prevent this; a manufacturer or distributor that has exited the New York generic opioid market, and thus avoided any Ratable Share for generic opioid sales in New York, would be able to undercut the price of those manufacturers that remain in the New York market and attempt to spread their OSA costs through incrementally higher prices in markets outside New York. Moreover, as discussed below, the dormant Commerce Clause would prohibit such an outcome.

The OSA Virtually Ensures Manufacturers Will Bear the Full Brunt of the Penalty

55. The OSA is drafted in a way that virtually ensures generic opioid manufacturers will bear the full burden of the OSA Ratable Share and thus the full loss associated with generic opioid sales in New York. Although the OSA prohibits passing the Ratable Share on to purchasers or consumers, it does not prohibit distributors from passing it back upstream to the manufacturer. Thus, wholesale distributors can make manufacturers bear the full Ratable Share burden.

56. AmerisourceBergen Corp., one of the three national distributors of prescription medications, wrote SpecGx on October 10, 2018, to notify SpecGx that AmerisourceBergen will, effective October 12, 2018, “no longer accept opioid product shipments at the National Distribution Center in Columbus, Ohio intended for redistribution to AmerisourceBergen distribution centers” in New York. The letter further states that “[i]f you would like to continue shipping opioid products to the [National Distribution Center] to New York . . . you agree to pay any tax, duty, levy, fee, assessment, tariff or any other charge of any nature imposed by any government authority on the sale or transfer of those opioid products”—*e.g.*, the OSA penalty.

Therefore, as a condition for distributing manufacturers' products in New York—where distributors would otherwise be responsible for the OSA penalty because they are effectuating the “first s[ale] or distribut[ion]” into New York—SpecGx must assume the burden of AmerisourceBergen’s Ratable Share. If other distributors follow suit, manufacturers—not distributors—would pay for the full \$100 million Opioid Stewardship Payment.

57. It is SpecGx’s understanding based upon internal sales data that the total Ratable Share for all of SpecGx opioid medications sold into New York, both by SpecGx and by distributors, would exceed SpecGx’s total revenues for the sale of such products, and therefore far exceed any profit SpecGx would make on those sales.

The Generic Pharmaceutical Market for Opioids Is Subject to Extensive Federal Regulation that Encourages the Development and Sale of Low-Priced Generic Alternatives to Brand-Name Drugs

58. The federal government, through multiple statutory schemes detailed herein, heavily regulates the approval, sale, and use of prescription medications, and in particular opioid medications. It exercises considerable control as to whether these drugs can be used at all, how they may be used, what quantities may be sold, and how patients can access these drugs safely and affordably, as well as requiring reimbursement for such regulated drugs by state Medicaid programs. Of particular relevance here, Congress has made particular judgments with respect to the approval and promotion of generic prescription medications and has encouraged manufacturers to seek and obtain approval for generic drugs to promote price competition and ultimately a more affordable option for patients nationwide.

59. **The FDCA Approval Process:** The Federal Food, Drug, and Cosmetic Act (“FDCA”) created the FDA for the purpose of “promot[ing] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated

products in a timely manner.” 21 U.S.C. § 393(b)(1). Under that statutory scheme, manufacturers “must gain approval” from the FDA “before marketing any drug in interstate commerce.” *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 476 (2013). But once a manufacturer obtains FDA approval as a safe and effective pharmaceutical drug, 21 U.S.C. § 393(b)(1), the FDCA leaves no room for states to countermand the FDA by prohibiting the sale of FDA-approved drugs for their FDA-approved purposes.

60. Before 1984, federal law required all pharmaceutical drug products, whether branded or generic, to undergo extensive and costly clinical testing prior to market entry. The significant costs associated with that process, however, created little incentive for drug manufacturers to replicate approved products, leaving hundreds of high-cost branded prescription drugs without an affordable generic equivalent. *See* Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 New Eng. J. Med. 1993, 1993 (2007).

61. **Hatch-Waxman Amendments:** Congress fundamentally addressed that troublesome imbalance through the passage of the Drug Price Competition and Patent Term Restoration Act in 1984, better known as the Hatch-Waxman Amendments. *See* Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of the U.S. Code). Those amendments were expressly intended “to make available more low cost generic drugs.” H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647. In fact, the Hatch-Waxman Amendments embody Congress’ attempt to strike “a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.” *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1282 (Fed. Cir. 2008) (citation omitted).

62. In pursuit of these competing ends, the Hatch-Waxman Amendments extended the life of brand-name manufacturers' patents covering on-market products, *see* 35 U.S.C. § 156, but permitted generic drug manufacturers to file an Abbreviated New Drug Application ("ANDA") based upon the data already submitted to the FDA in connection with the brand-name drug's approval, *see* 21 U.S.C. § 355(j). In other words, under the Hatch-Waxman Amendments, "generic drugs" can gain FDA approval simply by showing equivalence" to a drug "that has already been approved by the FDA," allowing "manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011). Approval of an ANDA confers a right secured by federal law to manufacture and market the covered product. *See* 21 U.S.C. § 355(j); 21 C.F.R. § 314.105(d).

63. Through its provision of generic alternatives to the significantly more expensive brand-name opioid medications pursuant to an FDA-approved ANDA, SpecGx directly participates in achieving the result expressly intended by the Hatch-Waxman Amendments—"mak[ing] available more low cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647. Indeed, in the last decade alone, "the U.S. healthcare system has saved \$1.67 trillion due to the availability of low-cost generics," like those manufactured by SpecGx. Ass'n for Accessible Meds., *Generic Drug Access & Savings in the U.S.* 5 (2017).

64. **Federal Medicaid Program:** In further effort to secure lower-cost medicine for Medicaid participants in particular, Congress created the Medicaid Drug Rebate Program ("MDRP"), Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4401, 104 Stat. 1388. As part of that initiative, for a prescription drug to be covered under Medicaid, the

manufacturer must sign a Medicaid National Drug Rebate Agreement (“NDRA”) with the Secretary of Health and Human Services on behalf of the States (except insofar as the Secretary has permitted individual manufacturer–state agreements). NDRAAs allow states to collect rebates on drugs purchased by the state Medicaid program, subject to the requirement that receiving states, *like New York*, cover *all* on-label uses of participating manufacturers’ FDA-approved drugs. 42 U.S.C. § 1396r-8(d).

65. DEA Aggregate Production Quota: The federal government has specifically deliberated as to the access and availability of opioid medications in particular. In an effort to deter and prevent the illicit diversion and improper use of FDA-approved opioid medications, Congress passed the Comprehensive Drug Abuse Prevention and Control Act of 1970. Pub. L. No. 91- 513, 84 Stat. 1236 (codified as amended at 21 U.S.C. §§ 801–971 (2012)). Under that federal legislation, the Drug Enforcement Agency (“DEA”) bears responsibility “for ensuring that all controlled substance transactions take place within the ‘closed system’ of distribution established by Congress.”¹⁷ The DEA fulfills this statutory mandate, in part, by setting nationwide annual production quotas for Schedule II opioids based on the anticipated medical, scientific, research, industrial, and export needs. 21 U.S.C. § 826 (2012). The DEA then grants an annual procurement quota to each manufacturer of Schedule II prescription opioids, and the manufacturer is precluded from manufacturing opioids once that procurement quota is reached.

CLAIMS FOR RELIEF

COUNT I

Declaratory/Injunctive Relief, under *Ex parte Young*, 209 U.S. 123 (1908), that the OSA Infringes SpecGx’s Rights Under Federal Law, Including the

¹⁷ DEA Practitioner’s Manual, *available at* https://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf.

Hatch-Waxman Amendments, and Is Unenforceable Under the Supremacy Clause, U.S. Const. art. VI, cl. 2

66. SpecGx realleges and incorporates by reference the preceding allegations in paragraphs 1 through 65 as though fully set out herein.

67. Under the Supremacy Clause of the United States Constitution, federal statutes are “the supreme Law of the Land.” U.S. Const. art. IV, cl. 2. No state law may “stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

68. “[I]f an individual claims federal law immunizes him from state regulation, the court may issue an injunction upon finding the state regulatory actions preempted.” *Armstrong v. Exceptional Child Center, Inc.*, 135 S. Ct. 1378, 1384 (2015) (citing *Ex parte Young*, 209 U.S. 123, 155–56 (1908)). Here, the Hatch-Waxman Amendments permit generic drug manufacturers to file ANDAs and, once approved, confer to generic manufacturers the rights to manufacture and sell those generic formulas of prescription medications.

69. The OSA stands as an obstacle to the accomplishment and execution of the full purposes and objectives of the Hatch-Waxman Amendments and is therefore preempted.

70. The purpose of the Hatch-Waxman Amendments (the Drug Price Competition and Patent Term Restoration Act) is to promote the entrance of generic manufacturers into the marketplace and provide affordable medications to consumers and government programs. Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of the U.S. Code). This purpose is evident from the law’s name, committee reports, and immediate effects. *See, e.g.*, H.R. Rep. No. 98-857, pt. II, at 9 (1984).

71. After deliberation, Congress determined that in exchange for extending the life of brand-name manufacturers’ patents that had gone through clinical trials and FDA review, 35

U.S.C. § 156, generic drugs would have an easier pathway to FDA approval and entry into the national marketplace. Specifically, the Hatch-Waxman Amendments allow for an abbreviated review process for generic drugs that could demonstrate “bioequivalence.” 21 U.S.C. § 355(j).

72. SpecGx has obtained FDA approval for the sale of its generic opioid products pursuant to this federal regulatory regime.

73. The OSA has the practical effect of forcing manufacturers of generic opioids (like SpecGx) approved by the FDA for nationwide sale to sell at a loss or exit the New York market. By imposing on generic manufacturers “Ratable Share” penalties that exceed revenue from sales attributable to the New York market and prohibiting manufacturers from passing on those penalties to purchasers, the OSA will drive FDA-approved generics like those of SpecGx out of the market in contravention of the FDCA and Hatch-Waxman Amendments’ purposes. In expelling generic manufacturers, the OSA effectively overrides the determination of the FDA that these opioids are safe and effective and the policy of Congress to encourage their availability to prescribers and their patients.

74. Moreover, the OSA effectively gives brand-name manufacturers (whose opioid products are sold at significantly higher prices than their generic equivalents) *both* extended patent rights *and* an oligopoly in New York, the fourth most populous state in the nation. This outcome runs directly contrary to the purpose of the Hatch-Waxman deal, which extended brand-name patent rights *while also* promoting the entry of generic drugs into the national marketplace. Rather than promote drug price competition, the OSA reduces the number of competitors and rewards brand-name actors. These ends conflict with those of the Hatch-Waxman Amendments—and, indeed, disrupt the entire statutory scheme.

75. Accordingly, the Act constitutes an impermissible attempt to limit (or even eliminate) availability of SpecGx's affordable, generic, FDA-approved medications, which is in direct conflict of the purposes and objectives of the Hatch-Waxman Amendments. Federal law therefore preempts the OSA.

COUNT II

Declaratory/Injunctive Relief, Under *Ex parte Young*, 209 U.S. 123 (1908), that the OSA Constitutes Impermissible Regulation by New York of Commerce Outside the State, in Violation of the Commerce Clause, U.S. Const. art. I, § 8, cl. 3

76. SpecGx realleges and incorporates by reference the preceding allegations in paragraphs 1 through 75 as though fully set out herein.

77. The Constitution not only vests Congress with the power “[t]o regulate Commerce with foreign nations, and among the several States,” U.S. Const. art. I, § 8, cl. 3, but also prohibits states from discriminating against interstate commerce, *see Healy v. Beer Inst., Inc.*, 491 U.S. 324 (1989). “The critical inquiry” under this “dormant” aspect of the Commerce Clause “is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State.” *Id.* at 336.

78. The OSA violates the dormant Commerce Clause because it has the practical effect of regulating commerce beyond the boundaries of the State of New York. Indeed, through the prohibition against passing on the cost of the Ratable Share to the “purchaser,” including the “ultimate user” of the medication, N.Y. Pub. Health Law § 3323(2), (10)(c), the OSA necessarily targets the pricing of out-of-state transactions.

79. As explained *supra*, the Ratable Share imposed on the MMEs contained in SpecGx’s highest volume generic brand opioid medications will far exceed the net revenues of these medications, meaning that the sale of generic opioids in New York would occur at an

effective loss. The OSA’s oppressive terms thus make it practically and economically unfeasible for SpecGx and other generic manufacturers to remain in the New York market without recouping the Ratable Share from outside New York.

80. The only possible way that any generic manufacturers could continue selling generic opioids in New York consistent with the OSA’s terms would be by externalizing the costs imposed by the OSA onto out-of-state purchasers. Put differently, in order to recover the economic losses they would sustain by continuing to participate in the New York opioid market, generic manufacturers would need to spread the cost of its Ratable Share penalties—monies that exclusively benefit the citizens of New York—to purchasers and patients residing *outside* of New York, through the form of price increases to those purchasers. Indeed, the OSA appears to require that any such price increase *only* apply to out-of-state purchasers, such that the out-of-state price would *exceed* the price in New York, in order to recoup the New York Ratable Share.

81. The OSA therefore has the undeniable effect of both controlling prices *outside of* New York and forcing New York’s sister states to bear the entire cost of legislation that benefits exclusively New York citizens. The OSA thus has the “practical effect” of “establishing ‘a scale of prices for use in other states,’” “control[ling] conduct” beyond the boundaries of New York, and projecting New York’s legislative hand into out-of-state transactions—the precise extraterritorial effects condemned by the dormant Commerce Clause. *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 334–37 (1989) (explaining that the Commerce Clause prohibits a state from “‘project[ing] its legislation into [other States] by regulating the price to be paid’ for [goods] in those States” (quoting *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 583 (1986))).

82. Indeed, the OSA has *already* “control[led] conduct” beyond New York’s boundaries. As explained above, at least one major distributor has refused to accept SpecGx’s (and presumably other generic manufacturers’) opioid medications for distribution into New York from its Ohio-based distribution hub, unless SpecGx and others agree to pay the OSA penalty on those medications destined for New York state. Accordingly, the OSA is effectively controlling a transaction between SpecGx and an out-of-state distributor location that would take place outside New York.

83. Furthermore, “the practical effect of the statute must be evaluated not only by considering the consequences of the statute itself, but also by considering how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation.” *Healy*, 491 U.S. at 336. On this point, the potentially deleterious effects are obvious: the imposition of restrictions analogous to the OSA by other states would have the potential to significantly erode normal (generally nationwide) pricing decisions in the pharmaceutical industry. Indeed, if multiple states enacted this type of legislation, the otherwise nationwide pricing model in the pharmaceutical market would fracture. Each state’s consumers would be forced to carry the cost of all the state programs except their own. And no manufacturer or distributor would be able to set a national price for their generic opioids. In other words, the proliferation of similar statutes would create the very sort of “potential regional and even national regulation of the pricing mechanism for goods . . . reserved by the Commerce Clause to the Federal Government.” *Id.* at 340.

84. These burdens to interstate commerce exceed any putative local benefit to residents of New York. The same benefit can be achieved through alternative fiscal measures. The

Constitution entrusts national economic policy to Congress precisely to avoid such outcomes. U.S. Const. art. I, § 8, cl. 3.

85. Because the OSA’s imposition of a penalty coupled with a prohibition against passing on the penalty has the “practical effect of extraterritorial control of commerce occurring entirely outside the boundaries of the state in question,” *Grand River Enters. Six Nations, Ltd. v. Pryor*, 425 F.3d 158, 168 (2d Cir. 2005) (citation omitted), the OSA violates the dormant Commerce Clause.

COUNT III

Declaratory/Injunctive Relief, Under *Ex parte Young*, 209 U.S. 123 (1908), that the OSA Infringes SpecGx’s Rights Under the Constitution and Laws of the United States, in Violation of 42 U.S.C. § 1983 and 42 U.S.C. § 1988

86. SpecGx realleges and incorporates by reference the preceding allegations in paragraphs 1 through 85 as though fully set out herein.

87. By seeking to implement and enforce the OSA, Defendants, acting under color of state law, have violated and, unless enjoined by this Court, will continue to violate the rights of SpecGx under federal statutes as well as to engage in interstate commerce free from unconstitutional state discrimination in violation of the dormant Commerce Clause.

88. An actual “Case or Controversy” exists because OSA’s various preempted and unconstitutional requirements requires SpecGx to take immediate action to avoid the OSA’s application, which creates a genuine, credible, and immediate threat that Defendants—acting in their official capacities under color of state law—will violate SpecGx’s federally protected rights.

89. SpecGx accordingly seeks a declaration that Defendants’ implementation or enforcement of the OSA would violate 42 U.S.C. § 1983. SpecGx also seeks reasonable attorneys’ fees pursuant to 42 U.S.C. § 1988.

PRAYER FOR RELIEF

WHEREFORE, SpecGx respectfully requests that this Court enter judgment in its favor and asks the Court:

- (A) For a declaration, pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, that the OSA's combination of imposing a penalty and prohibiting manufacturers from passing on that penalty infringes SpecGx's rights under the Constitution and Laws of the United States, including but not limited to infringing its rights under the Hatch-Waxman Amendments to sell federally licensed generic pharmaceuticals, in violation of the Supremacy Clause, and impermissibly regulating SpecGx's commercial relations outside New York, in violation of the dormant Commerce Clause, and that the OSA is therefore void and unenforceable as against SpecGx;
- (B) For a permanent injunction prohibiting Defendants from implementing or enforcing the OSA against SpecGx;
- (C) For such costs and reasonable attorneys' fees to which it might be entitled by law; and
- (D) For any other relief that the Court deems just and proper.

Dated: October 24, 2018

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